

IN THE UNITED STATES PATENT & TRADEMARK OFFICE
GROUP ART UNIT 1657

Applicant: Richard Melville FRANCE et al
Assignee: RegenTec Limited
Appln No: 10/550,151
Filed: September 20, 2005
For: POROUS MATRIX
Examiner: David M. Naff

DECLARATION

Honourable Commissioner of Patent & Trade Marks,

Sir,

Robin Andrew QUIRK declares as follows:

1. That he is Robin Andrew Quirk, who, together with Richard Melville France, invented the subject matter of the present application.
2. That he has read the Office Action dated February 22, 2010 and has considered the issues relating to the Written Description requirement and relating to the prior art documents US 6,841,617 (Jeong), US 6,290,729 (Slepian), US 6,818,018 (Sawhney) and US 6,129,761 (Hubbell).
3. That in his opinion the invention could have readily been carried out by the skilled artisan, such as himself, at the time of filing the application, based on what is described in the application. In particular, it would be understood by the skilled artisan from reading the application as filed how to carry out the invention using flowable solid particles for the material for the first phase.

4. That the application as filed provided a useful discussion of suitable characteristics of the material for the first phase. In particular, this information was provided at page 2 fifth paragraph, at the paragraph bridging pages 2 and 3, at the first full paragraph of page 3, and at page 9 fourth full paragraph, as well as in the Examples. From these sections the skilled artisan would appreciate that, inter alia, the invention could be carried out with the first phase material being: (i) solids that are sufficiently fluid to mix with and coat or carry the second phase material, (ii) solids that are fluid but tacky, (iii) particulate or powdered material, e.g. particulate or powdered material that is soft and tacky, or (iv) polymeric material that is tacky or fully liquefied.

5. That when using solid particles it is possible to introduce them into the body of the subject as solid particles within a liquid suspension, but it is equally feasible to add the particles into the body as a dry powder. The particles do not need to be fully melted or liquefied before delivery but rather there can be a partial melt or liquefaction at the surface of the particles only, such that the particles remain as discrete particles at all times. In other words, the particles can be viewed as becoming tacky semi-solids. These particles may be used in the form of a liquid suspension or as a dry powder. The particles can then fuse together in the body due to the change in surface properties of the particles that is caused with the change in temperature on introduction to the body of the subject, and solidify.

6. That it is therefore his belief that the application as filed provided the information required for the skilled artisan to comprehend and put into effect the invention, including the embodiments when the material for the first phase is a flowable solid.

7. That he has read the prior art document Jeong and understands that this document relates to a thermogelling biodegradable aqueous polymer solution which can be used in situ to form biodegradable implants. The thermogelling solution is designed to gel quickly at physiological conditions.

8. That it is clear to him that Jeong does not relate to a composition that is solidifiable to form a porous matrix, where the composition comprises a first polymeric phase which is a plastic solid or a solid in powder, grain or granule form, which can partially or fully liquefy, dissolve or melt or can become a tacky semi-solid. Equally, Jeong does not relate

to a composition where there is a second polymeric phase contained within and distributed through the first phase.

9. That in his opinion there is nothing in Jeong that indicates to the skilled artisan that the composition should comprise a polymeric phase which is a plastic solid or a solid in powder, grain or granule form, which can partially or fully liquefy, dissolve or melt or can become a tacky semi-solid. Instead, Jeong clearly teaches that the solidifiable material is a thermogelling solution.

10. That in his opinion there is also nothing in Jeong that indicates to the skilled artisan that a second material, which is a polymeric phase, could or should be contained in the thermogelling polymer solution. There is no motivation for a second polymeric material to be dispersed within this solution.

11. That Jeong describes the use of soft hydrogels as the material to form the implants. The nature of these materials means that they are not able to achieve macroporosity in the resultant solidified product. In contrast, the invention of the present application requires that a porous structure is formed by gaps between particles, or by the incomplete liquefaction of the first phase (in addition to any inherent porosity of the particles themselves). In other words, there must be macroporosity in the solidified matrix obtained by the invention of the present application.

12. That he has read the prior art document Slepian and understands that this document uses a biodegradable gelling liquid material, which is applied to the surface of tissue lumens to provide a barrier having either a controlled permeability to materials in the lumen and/or controlled release of incorporated bioactive agents. The material, in a fluid form, is positioned in contact with a tissue or cellular surface to be coated and is then stimulated to render it non-fluid.

13. That Slepian does not teach that the composition should comprise a polymeric phase which is a plastic solid or a solid in powder, grain or granule form, which can partially or fully liquefy, dissolve or melt or can become a tacky semi-solid. Instead, Slepian clearly teaches that the material is a gelling liquid material.

14. That Slepian also does not teach that a second polymeric material should beneficially be contained within and distributed through the solidifiable polymeric material. Instead, Slepian teaches, inter alia, that the polymeric material used as the biodegradable gelling material can be selected to achieve desired properties (such as the conditions under which it polymerises and its permeability), that multiple layers of polymeric material can be used, each containing different pharmacological agents, and that the physical guidance of cells can be achieved by including particles, ribbons or fibres which direct cell growth within the polymeric material. Slepian does not provide the skilled artisan with an instruction or teaching that he should include a second polymeric material dispersed within the solidifiable first polymeric material.

15. That Slepian mentions permeability, but this is a much smaller scale than macroporosity, where there are actual pores in a matrix structure. Indeed, Slepian uses hydrogels or organogels as the gelling material and the nature of these materials means that they are not able to obtain macroporosity. In contrast, the invention of the present application requires that a porous structure is formed by gaps between particles, or by the incomplete liquefaction of the first phase (in addition to any inherent porosity of the particles themselves); in other words there must be macroporosity.

16. That the teachings of Jeong and Slepian are therefore both missing any instruction to the skilled artisan (i) to use a first polymeric material which is a plastic solid or a solid in powder, grain or granule form, which can partially or fully liquefy, dissolve or melt or can become a tacky semi-solid, (ii) to use a second polymeric material that must be contained within and distributed through the first polymeric material and (iii) to use material that will obtain macroporosity in the solidified product, due to gaps between particles or the incomplete liquefaction of the first phase.

17. That there is nothing in either Jeong or Slepian that in any way highlights the benefit or desirability of achieving large, open interconnected pores, as is achieved in the invention of the present application.

18. That Sawinney or Hubbell do not provide any clear teaching that make the subject matter of the present application obvious.

19. That having read all the cited prior art documents, it cannot be seen to arrive at the subject matter of the present application from these documents, either considered alone or in combination.

The undersigned hereby declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made in the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such wilful false statements may jeopardise the validity of the application or any patent issued thereon.

Signed Robin Andrew Quirk

Date 2nd July '10

Robin Andrew QUIRK